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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/619,117	07/19/2000	Richard L Atkinson		1999

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EXAMINER

SALIMI, ALI REZA

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 11/25/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/619,117

Applicant(s)
Atkinson et al

Examiner
A. R. SALMI

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1648



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 15, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2, 3, 5, and 6 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 3, 5, and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Response to Amendment

This is a response to the Response, paper No.15, filed 11/15/2002. Claims 4, 7, and 8 have been canceled. Claims 2, 3, 5 and 6 are pending in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 2-3, 5-6 are rejected under 35 U.S.C. 112, second paragraph, for reasons of record advanced in the previous Office Action mailed 5/9/02. Applicants assert that no essential steps are omitted. Applicants further assert that since they are the first to have identified the fact that the adenovirus type 36p is strongly associated with obesity and is the cause of virality induced obesity, hence, this observation and its implementation in clinical testing entitle the applicants to a patent. They further add, this observation is unobvious and novel in the art. Applicants argue since there are many methodologies which can be used to detect the said virus hence they should be entitled to any and all method for detection of the virus. Applicants assert that creation of antibody to an epitope on a virus is no longer unobvious and is well within inhibit of one of ordinary skill in the art. Applicants argue what the applicants have demonstrated here is that there is now a reason to detect the virus since the virus is well known. Applicants add that for the first

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time they have demonstrated the said particular virus is associated with viral induced obesity.

Applicants argue there are two broad techniques described in the specification. One is to use an immunological technique based on antibody which recognizes an epitope on the virus. The other is to do a nucleic acid detection technique to identify RNA or DNA species indicative of the virus.

Applicant's argument as part of Paper NO. 15, filed 11/15/2002 has been considered fully, but they are not persuasive. In the first fold although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In addition, Applicants have already received patent protection for testing the presence of the adenovirus 36 type where its presence would indicate a possible link to obesity for their pioneering invention. Moreover Applicants are reminded, even the claims of pioneering inventors should be clear under 112, 2nd paragraph, so one can determine what is and is not intended (emphasis added). Why would patent protection be provided for imprecise, and ill defined invention where no one understands its precise boundaries?

Applicants are respectfully requested to review the 112, 2nd statute. Applicants are requesting patent protection for any and all general methods wherein the claims do not set forth any clear steps and elements that are needed to practice the general methods. Applicants do not address the rejections and concerns that were raised in the previous Office Action, and instead keep arguing a general techniques that are available to one of ordinary skill in the art. General techniques are meaningless without specific elements that are needed to be utilized in the general methods. For example, if the nucleic acid of claim 5 is not defined, how can a detection be made? If the

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conditions for claim 5 are not defined how can the detection be made? Applicants once again are reminded they are requesting a patent protection for a method of detecting and the elements that are needed to utilize in the methods should be clearly and concisely be present so one can know what the claims entail and how to practice the invention. In other words the boundaries of the elements that form the methods should be present in the claims. The claims cannot be practiced in a vacuum. Yes, raising antibodies are routine, however, if no epitopes are taught and the metes and bounds of the specific antigens are not taught then no antibodies can be raised, whether or not the technique is well known is immaterial. These are what applicants should consider addressing, and not the general techniques. Applicants are confusing the rejection raised by the Office, as if the office is asking for the applicants to teach the PCR or ELISA. Such is not the case. What is important, however, is/are the elements that are needed to be present in the method claims so one can practice the invention, and the steps and conditions of applying the elements systematically so one can determined what is being practiced. If the isolated nucleic acid is not defined, how is the detection made (emphasis added)? If the "probe" is not defined then how does the diagnosis made? If the conditions are not defined how is the probe going to detect anything? If the "epitope" is not present how can an antibody be raised? If the antibody is not taught the method cannot be practiced, whether the method is routine is irrelevant, since no detection occurs. As it was stated previously the claims are deficient for not reciting the conditions, and elements that are needed for practicing the methods. How is the detection made? If the ELISA assay is intended, then a specific antigen of Ad36p and antibodies are needed so one ordinary skill in the art can use

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to detect the virus. Presently the claims are vagues, uncelar, and indefinite since by reading the claims one would not be able to decipher the intended boundaries of elements and conditions to know what is and is not needed to practice the invention. The essential steps for detecting the virus Ad type 36p are missing. The claim should clearly state what steps and elements are needed to practice the invention. The rejection is maintained.

NEW GROUNDS OF REJECTION:

Claim Rejections - 35 USC § 112

Claims 2, 3, 5 are further rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is vague and indefinite, the intended metes and bounds of "epitope" is not defined. The claim has been interpreted in light of the specification and since the specification does not set forth any teaching of the metes and bounds of the intended epitope the claim is vague and indefinite. This affects the dependent claim(s).

In addition, Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the epitope, the antibodies against the epitope, etc... this affects dependent claim.

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Still further, Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how to isolate an epitope from feces, when to add antibodies, what is the control, the detection step is missing etc...

Claim 5 is vague and indefinite for recitation of "testing", how is the testing performed, visually? In addition, the claims is vague and indefinite for recitation of "detecting the presence of said sequences", what are the "said sequences"?

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

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1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-3014, or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A. R. Salimi

11/21/2002

AS
ALI R. SALIMI
PRIMARY EXAMINER